PTO/SB/21 (09-04)

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/289,000
Filing Date	February 25, 1997
First Named Inventor	Blatt, Gerald
Art Unit	3738
Examiner Name	P. Prebilic
Attorney Docket Number	016683-000120US

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- [X] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [X] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) (please identify below):

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Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Townsend and Townsend and Crew LLP		
Signature			
Printed name	J. Georg Seka		
Date	September 6, 2005	Reg. No.	24,491

CERTIFICATE OF TRANSMISSION/MAILING

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Signature			
Typed or printed name	Jane Welch	Date	September 6, 2005

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($) 250

Complete if Known	
Application Number	09/289,000
Filing Date	February 25, 1997
First Named Inventor	Blatt, Gerald
Examiner Name	P. Prebilic
Art Unit	3738
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METHOD OF PAYMENT (check all that apply)

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☒ Deposit Account Deposit Account Number: 20-1430 Deposit Account Name: Townsend and Townsend and Crew LLP

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Small Entity Fee ($)	Small Entity Fee ($)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____	-20 or HP = _____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____	-3 or HP = _____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round up to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other: Filing a brief in support of an appeal	250

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 24,491	Telephone 415-576-0200
Name (Print/Type)	J. Georg Seka		Date September 6, 2005

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TOWNSEND and TOWNSEND and CREW LLP

By: _____

PATENT

Attorney Docket No. 16683-1-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

GERALD BLATT

Application No. 09/289,000

Filed: February 25, 1997

For: JOINT TREATING METHOD

Examiner: P. Prebilic

Art Unit: 3738

APPELLANT'S BRIEF
UNDER 37 CFR §41.31

San Francisco, CA 94111
September 6, 2005

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant herewith submits this Appeal Brief pursuant to 37 CFR §41.31. Appellant authorizes the Commissioner to deduct the requisite fee of $250 pursuant to 37 CFR §41.20, and any additional fee that may be due from, and to credit any overpayment to, Deposit Account No. 20-1430.

A Notice of Appeal was filed on July 5, 2005 from the Final Rejection dated April 5, 2005.

I. REAL PARTY IN INTEREST:

The real party in interest of the present patent application is the inventor and owner thereof, Gerald Blatt.

II. RELATED APPEALS AND INTERFERENCES:

This application was the subject of Appeal No. 2003-1837. A Decision On Appeal was rendered September 26, 2003, and a copy thereof is attached hereto as an Appendix. The Decision involved then-pending claims 1-6, 8-10 and 24-31 and affirmed the Examiner's rejection of these claims.

Following the Decision, Appellant amended claims 1-6 and 24-26, which were held allowable in the Office Action dated March 9, 2004.

In a further Office Action dated September 24, 2004, the claims were again rejected for anticipation or obviousness over the Stone patent (5,306,311).

III. STATUS OF CLAIMS:

Claims 1-6 and 24-26 are pending, were rejected, and are on appeal.

Claims 7-23 are canceled.

IV. STATUS OF AMENDMENTS:

Following the Final Rejection, appellant filed an Amendment, Interview Summary and Request for Reconsideration Under 37 CFR 1.116 ("Amendment After Final").

The Amendment After Final made some changes to the claims in response to a rejection of the claims under 35 USC §112 and submitted arguments that the claims are neither anticipated by nor obvious over the Stone patent, alone or in combination with the Cohen patent (5,207,712).

In an Office Action dated June 21, 2005, the Examiner advised that the amendments made in the Amendment After Final overcame the Section 112 rejections and that the Amendment After Final would be entered for purposes of this appeal. The substantive rejection of the claims on appeal was maintained.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER:

The foundation for the present invention is Appellant's discovery that fibroblast, which develops at any site of injury and results from the transformation of a normal blood clot or

hematoma, through a series of histological microscopic changes called fibroplasias, when subjected to constant motion will change and develop into what is known as fibrocartilage. Fibrocartilage is white, smooth and looks very much like cartilage. (Page 3, lines 30-38).

Appellant concluded that fibrocartilage might be a durable and competent joint surface for the relief of pain, maintaining motion and adequate functional performance in at least the non-weight bearing, typically upper extremity joints. To accomplish this, a bioresorbable implant is placed between the joint surfaces and stimulates the formation of fibrocartilage as the implant is gradually dissipated and safely biologically resorbed by the body. (Page 4, lines 13-22). The underlying concept was to place the implant against the damaged, typically resected surface of the bone, and allow the joint to move so that the implant moves relative to the blood clot-covered bone surface, which should develop fibrocartilage. (Page 5, lines 2-4). Investigative studies have proven this to be the case. (Page 5, lines 8-12).

The invention is described with reference to in vivo tests performed on the shoulder joint of rabbits. To perform these tests, the shoulder joint was first prepared by exposing the joint, removing the humeral head 14, and replacing the latter with an implant 23 that was held in place by a stem extending into a bone cavity 21. As a result, the implant reconstituted the rounded surface of the humeral head that had been removed. (Page 7, lines 18-33).

The opposite, mating socket portion of the joint with its concave surface 30 served as the "damaged" joint that needed repair and was prepared by removing the articular cartilage thereon down to the cancellous bone to form a resected joint surface 34. Thereafter, the joint was surgically closed so that head 24 of implant 23 (Fig. 2) abutted the resected, concave surface 34. As a result, the surface formed by the head of the implant moved against the raw bony surface 34 each time the joint moved. (Page 7, line 34 to page 8, line 9). The joints prepared in this manner were studied after one year, one and half years and two years from the operation, and showed that after one year fibrocartilage 52 had formed (page 9, lines 5-7), and after two years from the original surgery an advanced form of fibrocartilage 58 had the appearance of actual hyaline cartilage, when the implant was substantially completely resorbed (page 9, lines 21-29). Thus, in the words of the inventor, "what appears to be necessary is that a

resected surface must rub against the bioresorbable implant to create the fibrocartilage". (Page 10, lines 31-33).

The present invention therefore requires that a bioresorbable implant be positioned opposite the cancellous bone that needs repair so that the face of the implant rubs against the cancellous bone to create the fibrocartilage.

VI. GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL:

As set forth in the Final Rejection:

1. Claims 1, 4-6 and 24-26 were rejected under 35 USC 102(b) for anticipation by Stone (5,306,311).

2. Claims 1, 4-6 and 24-26 were rejected under 35 USC §103(a) as obvious over Stone in view of Cohen (5,207,712).

3. Claims 2 and 3 were rejected under 35 USC §103(a) for obviousness over Stone, Cohen and Athanasiou (5,607,474).

VII. ARGUMENT:

All rejections of the claims rely on Stone as the principal reference.

1. *The disclosure of the Stone patent*

Stone principally discloses to repair a "hole" in surrounding healthy cartilage by placing and thereby implanting the disc 10 of patent Fig. 2 reproduced below in a correspondingly dimensioned hole "H" in the healthy cartilage 350 shown in patent Fig. 9 reproduced below.

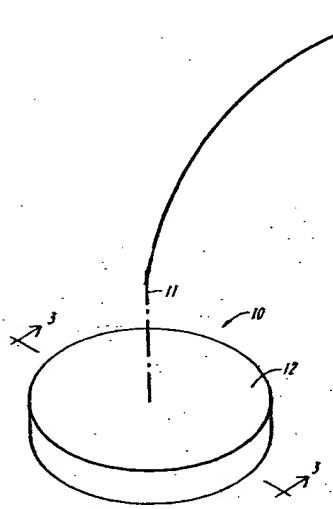

FIG. 2

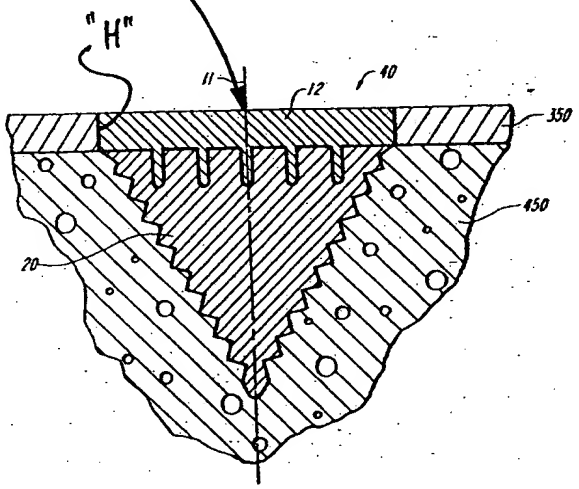

FIG. 9

Figs. 2 and 9 of Stone show the only cartilage that is being repaired, namely the cartilage that was removed from the healthy cartilage 350 to form hole "H" into which disc 10 is placed. There is no disclosure in Stone to use any part of the implant to repair cartilage on the opposite bone surface, which is not even shown in Stone.

The implant is flush with the surrounding cartilage, and the implant remains fixed to the bone "until sufficient tissue ingrowth occurs in the matrix 12" of implant 10. (Column 6, line 15).

Fig. 9 of Stone is a cross-sectional representation of the "prosthetic articular cartilage device" in place in a joint (column 5, lines 20-22) and shows a porous volume matrix 12 made of biocompatible and at least partially resorbable fibers (column 5, lines 37-48) in an opening or cut-out (hole "H" in Fig. 9) in the "natural articular cartilage 350" (column 15, lines 49-50). The articular cartilage device 10 that includes the porous volume matrix 12 can be held in place on the bone with a biological glue such as bone cement (column 5, lines 55-57). Alternatively, the matrix can be attached to a generally conical rigid base component 20 that is inserted into a corresponding pilot hole in the cancellous bone 450 (column 15, line 50) for "immediate fixation (by friction) and impaction and anchoring of device 10 into that bone" (column 6, lines 9-10).

To enhance the fixation of the alternative embodiment, Stone discloses that the base component 20 has ridges 14 on its outer surface, or is otherwise given a surface roughness. (Column 6, lines 2-8).

Thus, Stone discloses, as is illustrated in Fig. 9, to repair damaged articular cartilage surrounded by healthy articular cartilage 350, as is seen in Fig. 9. The implant is cemented to the bone, or is anchored to the bone with base component 20. Accordingly, the implant is rigid and immovable relative to the surrounding cartilage 350 and the underlying bone 450. Indeed, this is an absolutely necessity for Stone, because the implant "acts as a scaffold for generating articulate cartilage tissue whose ingrowth is encouraged by the physical characteristics of the implanted device". (Column 5, lines 34-38). Regenerating articular cartilage necessarily originates from the surrounding healthy cartilage and/or the underlying cancellous bone. If the implant were allowed unrestricted slidable motion relative to the surrounding healthy cartilage or underlying bone, indeed, if any relative motion were to take place, the regeneration of articular cartilage could not proceed and would be impossible to attain.

Thus, it bears repeating that Stone's disclosure is strictly limited to regenerating articular cartilage on the surface of the bone into which the implant is anchored. There is no disclosure in Stone whatsoever to regenerate articular cartilage on the bone of the joint opposite the bone on which the implant is fixed.

2. *Claims 1, 4-6 and 24-26 are not anticipated by Stone*

A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). MPEP §2131.

Independent claims 1 and 24-26 are similar, and claim 1 can be viewed as typical of these claims, which is worded as follows:

> A method for treating a joint formed by opposing bones having first and second mating joint surfaces so that relative slidable joint motion between the bones is permanently maintained comprising the following steps:
>
> removing at least a portion of the first joint surface to expose a cancellous bone surface covered by a layer selected from the group consisting of at least one of blood clot and hematoma;
>
> selecting an implant made of bioresorbable material only and having a face adapted to face the cancellous bone surface;
>
> placing the bioresorbable implant between the second joint surface and the cancellous bone surface so that the face is in slidable contact with the layer covering the cancellous bone surface and the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface while permitting unrestricted relative slidable motion between the face and the cancellous bone surface including the layer covering it;
>
> using the joint while allowing resorption of the implant and causing unrestricted slidable motions between the face and the layer covering the cancellous bone surface to stimulate the formation of fibroblast from the layer covering the cancellous bone surface so that the fibroblast can progress into fibrocartilage as the implant is resorbed, the fibrocartilage replaces the implant during such resorption, and thereafter relative slidable motion between the bones along the fibrocartilage occurs when using the joint.

Claim 1 as well as claims 24-26 distinguish between the opposing joint surfaces and refer to them as the "first and second mating joint surfaces" and require that at least a portion of the first joint surface is removed to expose cancellous bone.

Claim 1 then recites that the bioresorbable implant is placed between the cancellous bone (on the first joint surface) and the second joint surface "so that the face is in

slidable contact with the layer [of blood clot or hematoma] covering the cancellous bone surface ...."

Although Stone shows the two joint surfaces of a knee in Fig. 1, the disclosure of Stone is entirely limited to the treatment of a single surface of a joint by cementing or frictionally impacting the implant into the associated bone. There is no suggestion and no disclosure anywhere in Stone what happens to the surface of the joint opposite the bone shown in Fig. 9 which receives the implant. There is no disclosure in Stone that the opposite bone surface requires any treatment and/or how the opposite bone surface should be treated. There is also no disclosure in Stone what one would have to do to repair cartilage on the non-illustrated bone opposite the bone on which the implant is fixed.

In view of the absence of any relevant disclosure, and since the implant is affixed to bone 450 to regenerate damaged cartilage overlying that bone, and not the opposite bone, Stone does not disclose or in any form suggest the invention as recited in claim 1. For this reason alone, Stone does not anticipate claim 1.

The same observation applies to independent claims 24-26, all of which recite that the implant is placed between opposite bone surfaces so that it can slidably move relative to the degenerated cancellous bone surface.

Claim 1 further requires that the implant, once placed in the bone, must permit "unrestricted relative slidable motion between the face [of the implant] and the cancellous bone surface [of the first joint surface] including the layer [of blood clot or hematoma] covering it ...."

As already mentioned, Stone discloses that the implant, and in particular the porous volume matrix 12 thereof, is either cemented to the bone, or is immediately fixed by friction and impaction into the bone. (Column 6, lines 8-10). This allows the implant to act "as a scaffold for regenerating articular cartilage tissue". (Column 5, lines 35-36). If relative slidable motion between the implant and the surrounding articular cartilage 350 and bone 450 were to take place, articular cartilage tissue could not regenerate into the scaffold formed by the implant.

Thus, Stone does not disclose or in any form suggest to permit "unrestricted relative slidable motion between the face and the cancellous bone surface", as recited in claim 1.

The same applies to independent claims 24-26, which have identical or very similar limitations permitting unrestricted relative slidable motion between the face of the implant and the exposed cancellous bone surface.

For this further reason, Stone does not anticipate claim 1, or independent claims 24-26.

Claim 1 additionally recites "using the joint ... and causing unrestricted slidable motions between the face [of the implant] and the layer covering the cancellous bone surface [of the first joint surface] to stimulate the formation of fibroblast from the layer covering the cancellous bone ...."

The implant 10, and in particular the porous volume matrix 12 of Stone, is fixed by cementing it to the bone, or frictionally fixing and impacting it into the bone. Although Stone's implant can be used immediately following its implantation, because the "softer matrix 12 [remains] flush with the surface of the surrounding area existing articulate cartilage of the bone into which the prosthetic device 12 is being implanted" (column 6, lines 11-13), during use of Stone's joint there can be no "unrestricted slidable motions between the face [of the implant] and the layer covering the cancellous bone" because the implant and the bone are immediately fixed and firmly secured to each other.

For this additional reason, Stone does not anticipate claim 1.

The same applies to independent claims 24-26, which are similarly, and in part identically, worded as claim 1 with regard to slidably moving the implant face relative to the exposed cancellous bone surface.

Thus, Stone does not anticipate independent claims 1 and 24-26.

In this context, appellant repeats that Stone has no disclosure whatsoever how the implant 10 secured to bone 450 and cartilage 350 (Fig. 9) can in any way affect the opposite bone. Stone has no disclosure and nowhere suggests that the implant shown in Fig. 9 could in any way regenerate articular cartilage or, for that matter, fibroblast on the opposite bone surface. Stone's disclosure is strictly limited to reconstituting the earlier mentioned "hole" in the cartilage by anchoring a porous volume matrix 12 to the bone and permitting articular cartilage tissue to

regenerate into that matrix. Thus, the fact that the face of Stone's porous matrix 12 can slidably move relative to the opposite bone surface is of no consequence with regard to the present invention because Stone has no concern for and does not even mention the opposite bone surface or that the opposite bone surface requires cartilage repair, and how that could be attained.

In support of the anticipation rejection of the claims, the Examiner argued in the Final Rejection that the "slidable contact of the implant with the bone surface is considered inherent for the same reason that such contact is present in Applicant's surface; i.e. the same implant structure as claimed must have motion as Stone because it is the same structure".

As was discussed above, the implant structure, and in particular the method of implantation recited in the independent claims, is not the same as that disclosed in Stone. With a full understanding of how the implant of Stone is implanted and functions, it is apparent that the two are radically different and bear no resemblance. The Examiner's reliance on the inherency of the slidable contact is factually erroneous and misplaced and cannot support the anticipation rejection of the claims.

Moreover, in order to repair the ("first") bone surface opposite the bone of Stone which holds the implant, the first joint surface must be removed "to expose a cancellous bone surface" as recited in the independent claims. There is no suggestion in Stone to remove anything from the bone opposite the implant, and without such removal no fibroblast would form on the first surface. The present invention is therefore not inherent in Stone as argued by the Examiner.

The Examiner further supported the anticipation rejection because of his view that "the Stone implant would inherently be able to rotate about its central axis while within the bone cavity because the threads thereon can be concentric or helical and self-tapping". This observation is explicitly contradicted by Stone, which discloses that the implant is either cemented into the bone, or it is immediately fixed by friction and impaction into the bone. Clearly, that is to prevent any relative motion between the implant and the bone so that the prosthetic articular cartilage acts as a scaffold into which articular cartilage tissue can regenerate. An argument that such an arrangement "inherently allows the implant to rotate about its central axis" is contrary to both reason and logic. Moreover, even if that were true, which it is not,

rotation about an axis does not permit "unrestricted relative slidable motion between the face [of the implant] and the cancellous bone surface", as recited in the independent claims.

Thus, the Examiner's reliance on an "inherent" ability of Stone's implant to rotate about its axis is factually erroneous and misplaced and does not support the anticipation rejection of the independent claims.

3. *Claims 1, 4-6 and 24-26 are not obvious over Stone in view of Cohen*

The claims were alternatively rejected for obviousness over Stone and Cohen in the event Stone is considered as not disclosing a completely resorbable implant because Cohen teaches "to make similar implants out of completely resorbable materials".

However, Cohen does not teach or in any form suggest to place an implant between the two joint surfaces so that the face of the implant is in slidable contact with the cancellous bone, while permitting unrestricted relative slidable motion between them, as is recited in the independent claims. Cohen therefore also does not teach or suggest to use the joint and thereby cause "unrestricted slidable motion between the face [of the implant] and the layer covering the cancellous bone", as recited in the independent claims. Cohen's implant does not provide unrestricted slidable motions between the face and the opposing bone. Indeed, the recitation that the implant permits unrestricted slidable motions between the face and the opposing bone is what led to the allowance of these claims over Cohen after the Board's Decision of September 23, 2003 (attached as an Appendix) and before the claims were rejected over the Stone patent.

Accordingly, Appellant submits that claims 1, 4-6 and 24-26 are not obvious over Stone and Cohen.

4. *Claims 2 and 3 are not obvious over Stone, Cohen and Athanasiou*

Stone and Cohen were applied against these claims in the same manner as they were applied against the remaining claims discussed in the previous subsection of these arguments. Athanasiou was only relied on as showing that it was known to make "similar joint implants out of lactic acid copolymers".

Claims 2 and 3 depend from claim 1 and, therefore, incorporate all limitations of that claim. Since Athanasiou does not supply what is missing from Stone and Cohen with regard to the parent claim of claims 2 and 3, the claims become allowable by virtue of their dependency from that claim.

Thus, claims 2 and 3 are not obvious over Stone, Cohen and Athanasiou.

VIII. CONCLUSION:

In view of the foregoing, Appellant submits that:

1. Claims 1, 4-6 and 24-26 are not anticipated by Stone.

2. Claims 1, 4-6 and 24-26 are not obvious over Stone in view of Cohen.

3. Claims 2 and 3 are not obvious over Stone in view of Cohen and Athanasiou.

Accordingly, Appellant requests that the rejection of claims 1, 4-6 and 24-26 be reversed.

Respectfully submitted,

J. Georg Seka
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APPENDIX I - CLAIMS ON APPEAL

Claim 1: A method for treating a joint formed by opposing bones having first and second mating joint surfaces so that relative slidable joint motion between the bones is permanently maintained comprising the following steps:

removing at least a portion of the first joint surface to expose a cancellous bone surface covered by a layer selected from the group consisting of at least one of blood clot and hematoma;

selecting an implant made of bioresorbable material only and having a face adapted to face the cancellous bone surface;

placing the bioresorbable implant between the second joint surface and the cancellous bone surface so that the face is in slidable contact with the layer covering the cancellous bone surface and the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface while permitting unrestricted relative slidable motion between the face and the cancellous bone surface including the layer covering it;

using the joint while allowing resorption of the implant and causing unrestricted slidable motions between the face and the layer covering the cancellous bone surface to stimulate the formation of fibroblast from the layer covering the cancellous bone surface so that the fibroblast can progress into fibrocartilage as the implant is resorbed, the fibrocartilage replaces the implant during such resorption, and thereafter relative slidable motion between the bones along the fibrocartilage occurs when using the joint.

Claim 2: The method of claim 1 further comprising the step of selecting the bioresorbable implant made of a polymer of lactic acid.

Claim 3: The method of claim 2 wherein the selecting step is carried out by selecting a lactic acid copolymer.

Claim 4: The method of claim 1 further comprising the steps of:

estimating the period time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size, shape and material according to said period of time.

Claim 5: The method of claim 1 further comprising the step of ensuring the exposed cancellous bone surface and the face of the bioresorbable implant placed against said cancellous bone surface have complementary surface shapes.

Claim 6: The method of claim 5 wherein the ensuring step includes the step of selecting curved surface shapes as said complementary surface shapes.

Claim 24: A method for treating at least one degenerated surface on a cancellous bone, the cancellous surface being one of first and second relatively slidably movable surfaces defining a non-weight bearing body joint, so that slidable joint motion between the bones is permanently maintained, the method comprising the steps of resecting the bone to form the at least one degenerated cancellous bone surface to expose a layer selected from the group consisting of at least one of blood clot and hematoma thereon, placing an implant made of bioresorbable material only between the at least one degenerated cancellous bone surface and the second surface to thereby space the surfaces apart, providing the implant with at least one face which is opposite and shaped complementary to at least one degenerated cancellous bone surface so that the implant can slidably move without restriction relative to the at least one degenerated cancellous bone surface, allowing the face to slidably move relative to the at least one degenerated cancellous bone surface and the layer selected from the group consisting of at least one of blood clot and hematoma without restriction to thereby stimulate the growth of fibroblast from the layer selected from the group consisting of at least one of blood clot and hematoma on the at least one cancellous surface and the conversion of the fibroblast into fibrocartilage during the allowing step, and gradually resorbing the implant during the allowing step so that, upon resorption of the implant, the fibrocartilage forms at least one of the body joint defining surfaces.

Claim 25: A method for treating a non-weight bearing joint having first and second mating joint surfaces so that slidable joint motion between the bones is permanently maintained comprising the following steps:

removing at least a portion of the first joint surface to generate an exposed cancellous bone surface covered by a layer selected from the group consisting of at least one of blood clot and hematoma;

placing an implant made of bioresorbable material only between and in contact with the exposed cancellous bone surface and the second joint surface so the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface;

providing the implant with a face which is opposite the exposed cancellous bone surface;

permitting unrestricted relative slidable motion between the face and the exposed cancellous bone surface;

using the joint and slidably moving the face relative to the exposed cancellous bone surface and the layer without restriction caused by the implant;

allowing formation of fibroblast from the layer and of fibrocartilage from the fibroblast while using the joint as the implant is resorbed and continuing to slidably move the face relative to the exposed cancellous bone surface;

following the complete resorption of the implant continuing to slidably move the second surface along the formed fibrocartilage;

estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size, shape and material according to said period of time.

Claim 26: A method for treating a joint having first and second mating joint surfaces carried by cancellous bone so that slidable joint motion between the bones is permanently maintained comprising:

removing at least a portion of the first joint surface to expose a cancellous bone surface covered by a layer selected from the group consisting of at least one of blood clot and hematoma thereon;

forming a cavity into the medullary canal of the cancellous bone carrying the second joint surface;

selecting an implant made of bioresorbable material only and configured to fit between the cancellous bone surface and the second joint surface, the implant having a face, a backside and a stem portion extending from the backside and configured to fit within said cavity;

inserting the stem portion into the cavity and placing the bioresorbable implant between the cancellous bone surface and the second joint surface so the implant initially keeps said surfaces spaced apart and the face is freely slidably movable relative to the cancellous bone surface and the layer;

using the joint while allowing complete resorption of the implant and permitting unrestricted relative slidable motion between the face and the cancellous bone surface and the layer; and

allowing formation of fibroblast from the layer and of fibrocartilage from the fibroblast while using the joint as the implant is completely resorbed to replace the implant and maintain relative slidable motion between the bones along the formed fibrocartilage.

APPENDIX II - DECISION BY BOARD OF PATENT APPEALS AND INTERFERENCES

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 40

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GERALD BLATT

Appeal No. 2003-1837
Application No. 09/289,000

ON BRIEF

Before GARRIS, OWENS, and POTEATE, Administrative Patent Judges.

GARRIS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal which involves claims 1-6, 8-10 and 24-31. These are all of the claims remaining in the application.

The subject matter on appeal relates to a method for treating a joint formed by opposing bones having first and second mating joint surfaces so that relative slidable joint motion

between the bones is permanently maintained. The method includes the steps of placing a bioresorbable implant between and in contact with the cancellous bone surface of a first joint and a second joint surface so that the face of the implant is opposite the cancellous bone surface and the implant initially keeps the cancellous bone surface spaced apart from the second joint surface while permitting relative slidable motion between the face and the cancellous bone surface, using the joint while allowing resorption of the implant and causing slidable motions between the face and the cancellous bone surface, and allowing formation of fibroblast at the cancellous bone surface while using the joint so that the fibroblast progresses into fibrocartilage as the implant is resorbed. Further details of this appealed subject matter are set forth in representative independent claims 1 and 8 which read as follows:

1. A method for treating a joint formed by opposing bones having first and second mating joint surfaces so that relative slidable joint motion between the bones is permanently maintained comprising the following steps:

removing at least a portion of the first joint surface to expose a cancellous bone surface;

selecting a bioresorbable implant having a face adapted to face the cancellous bone surface;

placing the bioresorbable implant between and in contact with the second joint surface and the cancellous bone surface so that the face is opposite the cancellous bone surface and the

implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface while permitting relative slidable motion between the face and the cancellous bone surface;

using the joint while resorbing the implant and causing slidable motions between the face and the cancellous bone surface; and

forming fibroblast at the cancellous bone surface while using the joint so that the fibroblast progresses into fibrocartilage as the implant is resorbed, the fibrocartilage replaces the implant during such resorption, and thereafter relative slidable motion between the bones along the fibrocartilage occurs when using the joint.

8. A method for treating a substantially non-weight bearing arthritic joint having first and second mating joint surfaces so that relative slidable joint motion between the bones is permanently maintained comprising the following steps:

removing at least a portion of the first and second joint surfaces to expose first and second cancellous bone surfaces;

selecting a bioresorbable implant having first and second implant faces corresponding to the first and second cancellous bone surfaces;

placing the first and second implant faces of the bioresorbable implant between and against the first and second exposed cancellous bone surfaces so as to permit relative slidable motion between the first and second faces and the first and second cancellous surfaces;

using the joint and causing slidable motions between the face and the first cancellous surfaces; and

while using the joint forming fibrocartilage at each said cancellous bone surface as the implant is resorbed to thereby replace the implant during such resorption and enable slidable motion between the bones along the formed fibrocartilage.

The references set forth below are relied upon by the examiner in the section 102 and section 103 rejections before us:

Delcommune et al. (Delcommune)	5,007,939	Apr. 16, 1991
Cohen	5,207,712	May 4, 1993

Claims 1, 4-6, 8-10 and 24-31 are rejected under 35 U.S.C. § 102(b) as being anticipated by or alternatively under 35 U.S.C. § 103(a) as being obvious over Cohen; and claims 2 and 3 stand rejected under 35 U.S.C. § 103(a) as being obvious over Cohen in view of Delcommune.[1]

We refer to the brief and reply brief and to the answer for a complete exposition of the differing viewpoints expressed by the appellant and by the examiner concerning these rejections.

OPINION

For the reasons set forth in the answer and below, we will sustain each of these rejections.

It is the examiner's basic position that the method of Cohen's Figure 10 embodiment would necessarily and inherently practice each of the here claimed method steps including the step of causing slidable motions between the implant face and the cancellous bone surface. As support for his position concerning

[1] On page 5 of the brief, the appellant states that "[a]ll claims stand or fall together." In addition, the appellant has proffered no separate arguments concerning the separate rejection of dependent claims 2 and 3. Therefore, in assessing the merits of the above noted rejections, we will focus on independent claim 1 as representing the claims on appeal. See 37 CFR § 1.192(c)(7)(8)(2002) and compare In re McDaniel, 293 F.3d 1379, 1382-83, 63 USPQ2d 1462, 1464-65 (Fed. Cir. 2002).

this last mentioned claim feature, the examiner refers to patentee's teaching that, "[a]fter placement [of the implant], the stability and position of the toe is checked" and that "[f]lexion and extension of the joint should not result in dislocation of the implant" (column 4, lines 37-39). On the other hand, it is the appellant's fundamental argument that, not only does the Cohen reference contain no teaching or suggestion regarding this slidable motion feature, but that the configuration and placement of patentee's Figure 10 implant are such that slidable motion between the implant face and the cancellous bone surface as required by each of the independent claims on appeal would be impossible. Moreover, as support for this argument, the appellant on pages 10-13 of the brief refers to the Blatt and Smith declarations of record.

In response to this argument, the examiner reiterates his position regarding the aforequoted flexion disclosure of Cohen and emphasizes that, "since the fit of the holes [i.e., in the bone] and rod o[r] shaft of Cohen are [sic, is] not tight . . ., the Examiner posits that at least some slight motion is possible to the extent required by the present claim language" (answer, page 6). The appellant rebuts the examiner's last mentioned point by contending that "[t]he Cohen patent nowhere states that

a tight fit between the holes and implant shafts is not required" (reply brief, page 2). This contention by the appellant clearly is without merit. At lines 33-35 in column 4, patentee explicitly teaches that "a tight fit between holes and implant shafts is not required." Further, we perceive well taken rationale in the examiner's position that, in the absence of a tight fit between holes and implant shafts, at least some degree of slidable motion between the face (i.e., sphere 72) of patentee's Figure 10 implant and the cancellous bone surface would be possible. As properly indicated in the answer, even a slight degree of slidable motion would satisfy the claim requirement under consideration. Finally, it is significant that the aforementioned Blatt and Smith declarations do not address this specific aspect of the Cohen disclosure.

In light of the foregoing, it is our determination that the examiner has established a reasonable basis for believing that Cohen's method would necessarily and inherently practice the slidable motion step required by the independent claims on appeal notwithstanding a full consideration of the appellant's position to the contrary. Under these circumstances, it is appropriate that the appellant be required to prove that the Figure 10 embodiment of patentee's method, in the absence of a tight fit

between holes and implant shafts as discussed above, would not actually practice the here claimed slidable motion feature. Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the inability of the Patent and Trademark Office to manufacture products or to obtain prior art products in order to thereby compare Cohen's aforementioned method with the here claimed method. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). On the record before us, the appellant has submitted no proof that the practice of Cohen's method in the absence of a tight fit between holes and implant shafts would fail to result in slidable motion as required by the independent claims on appeal.

Consequently, it is our ultimate determination that the examiner has established a prima facie case of unpatentability which the appellant has not successfully rebutted with argument and/or evidence of patentability. See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). We shall sustain, therefore, the examiner's section 102 and section 103 rejections of claims 1, 4-6, 8-10 and 24-31 based on the Cohen reference. The section 103 rejection of claims 2 and 3 based on

Cohen in view of Delcommune also will be sustained since the appellant has not separately contested this rejection on the record before us.

Other Issues

The method defined by appealed independent claim 8 and by the claims which depend therefrom requires placing first and second implant faces of a bioresorbable implant between and against first and second exposed cancellous bone surfaces "so as to permit relative slidable motion between the first and second faces and the first and second cancellous surfaces" (claim 8). However, our study of the appellant's specification and drawing raises the issue of whether one with an ordinary level of skill in this art would be able to practice the claim 8 requirement "so as to permit relative slidable motion between the first and second faces and the first and second cancellous surfaces" (i.e., as required by the first paragraph of 35 U.S.C. § 112).

With reference to Figures 2 and 3 of the appellant's drawing and the specification disclosure relating thereto, the implant 23 is "mounted to resected head 14 of the humerus with . . . stem 26 of implant 23 locking into cavity 21 formed in the medullary canal of the humerus" (specification, page 7, lines 28-32; emphasis added). While this arrangement would permit slidable

motion between the implant face at head 24 and the cancellous surface 34 of socket 30, it is clear that slidable motion would not be permitted between the other implant face (i.e., the flat portion beneath head 24) and the cancellous surface 20 of head 14. That is, the implant face beneath head 24 would not be capable of slidable motion relative to cancellous surface 20 because, according to the appellant's aforequoted disclosure, implant 23 is mounted to head 14 by way of stem 26 locking into cavity 21.

Under these circumstances, it appears that the method and implant described in the appellant's original disclosure would not be capable of practicing the claim 8 method requirement "so as to permit relative slidable motion between the first and second faces and the first and second cancellous surfaces." In essence, the implant face which is adjacent cancellous surface 20 would not be capable of slidable motion relative to this surface for reasons analogous to those advanced by the appellant with respect to the Figure 10 implant of Cohen. While the appellant's reasoning is unpersuasive with respect to the Cohen implant as

explained above, this reasoning is applicable and convincing with respect to the implant disclosed in the subject specification.[2]

In addition to the enablement issue mentioned previously, these circumstances raise the issue of whether the subject matter now claimed by the appellant in claim 8 and the claims which depend therefrom complies with the written description requirement set forth in the first paragraph of 35 U.S.C. § 112. These circumstances may raise yet a further issue under the second paragraph of section 112 since the requirements thereof demand that a claim must accurately define an applicant's invention. See In re Knowlton, 481 F.2d 1357, 1365-66, 178 USPQ 486, 492 (CCPA 1973).[3]

These issues should be addressed by the examiner and the appellant in any further prosecution that may occur.

Summary

The decision of the examiner is affirmed.

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[2] It is here appropriate to emphasize that the appellant's disclosure expressly describes the implant as being mounted and locked into bone cavity 21 whereas, in opposing contrast, Cohen's disclosure expressly teaches "a tight fit between holes and implant shafts is not required" (column 4, lines 33-35).

[3] A section 112, second paragraph, issue also may be raised by dependent claim 9 since the phrase "the first implant surface" lacks antecedent basis (e.g., see In re Altenpohl, 500 F.2d 1151, 1156-57, 183 USPQ 38, 43 (CCPA 1974)). Apparently, this phrase should read --the first implant face--.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Bradley R. Garris)
Administrative Patent Judge)
)
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)
Terry J. Owens) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
)
Linda R. Poteate)
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BRG:tdl

Appeal No. 2003-1837
Application No. 09/289,000

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